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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/980,116	11/30/2001	Heiko Apfel	100564-00090	8152

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EXAMINER	
GIBBS, TERRA C	

ART UNIT	PAPER NUMBER
1635	

DATE MAILED: 04/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/980,116	APFEL ET AL.	
	Examiner	Art Unit	
	Terra C. Gibbs	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-58 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-58 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-58 are pending in the instant application.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-20, drawn to a method for providing agents for the detection, prevention and/or therapy of microbial infections, classifiable in class 435, subclass 7.8.

II. Claims 21-33, drawn to a method for identifying essential microbial genes, classifiable in class 435, subclass 6.

III. Claims 34, 35, 36, 38, 39, 40, 41, 42, and 58, drawn to a nucleic acid coding for an essential secretory gene for *Helicobacter*, classifiable in class 536, subclass 23.1.

IV. Claim 37, drawn to a nucleic acid depicted in SEQ ID NOs: 1 to 245, classifiable in class 536, subclass 24.5.

V. Claim 43, drawn to a mutant library, classifiable in class 536, subclass 23.7.

VI. Claims 44-47, drawn to a polypeptide encoded by a nucleic acid coding for an essential secretory gene for *Helicobacter*, classifiable in class 530, subclass 350.

VII. Claim 48, drawn to an inhibitory molecule, classifiable in class 536, subclass 22.1.

VIII. Claim 49, drawn to a method for producing a polypeptide encoded by a nucleic acid coding for an essential secretory gene for *Helicobacter*, classifiable in class 435, subclass 69.1.

IX. Claim 50, drawn to the use of a polypeptide encoded by a nucleic acid coding for an essential secretory gene for *Helicobacter*, classifiable in class 435, subclass 29.

X. Claim 51, drawn to an antibody that is specific a polypeptide encoded by a nucleic acid coding for an essential secretory gene for *Helicobacter*, classifiable in class 424, subclass 134.1.

Claims 52-57 link(s) inventions of Groups III, IV, VI, VII, and X. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claims 52-57. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

The inventions are distinct, each from the other because of the following reasons:

Inventions of Groups I and II are unrelated, each from the other. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions have different modes of operation and have different functions. Invention I is distinct from Invention II because they are drawn to different methods. For example, Group I is drawn to a method for providing agents for the prevention of microbial

infections, whereas Group II is drawn to a method for identifying essential microbial genes. They are materially distinct methods which differ at least in objectives, method steps, reagents and/or dosages and/or schedules used, response variables, and criteria for success. Thus, they are patentably distinct from each other.

Inventions of Groups III and IV are unrelated, each from the other. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions are drawn to nucleic acids coding for an essential secretory gene of *Helicobacter* and specific nucleic acids depicted in SEQ ID NOs: 1 to 245. The nucleic acids of Group III differ from the nucleic acids of Group IV since they have different physical properties and chemical structures. Thus, they are unrelated and patentably distinct from each other.

Inventions of Groups IV and V are unrelated, each from the other. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions are drawn to nucleic acids depicted in SEQ ID NOs: 1 to 245 and a mutant library comprising nucleic acids coding for an essential secretory gene of *Helicobacter*. The nucleic acids of Group IV differ from the nucleic acids of Group V since they have different physical properties and chemical structures. Thus, they are unrelated and patentably distinct from each other.

Inventions of Groups III, VI, and X are unrelated, each from the other. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have

different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions are drawn to nucleic acids coding for an essential secretory gene of *Helicobacter*, a polypeptide encoded by a nucleic acids coding for an essential secretory gene of *Helicobacter*, and an antibody that is specific a polypeptide encoded by a nucleic acid coding for an essential secretory gene for *Helicobacter*, respectively. It is acknowledged that various processing steps may cause the nucleic acids of Group III to be directed to the polypeptide of Group VI, however, the completely separate chemical types of the inventions of Groups III and VI supports the undue search burden if both were examined together. The separate chemical types of the invention of Groups III, VI, and X are further supported by their different classification and separate status in the art. Additionally, polypeptides have been most commonly, albeit not always, separately characterized and published in the Biochemical literature, thus significantly adding to the search burden if searched together, as compared to being searched separately. For these reasons, each of Groups III, VI, and X are separate and distinct from each other.

Inventions of Groups VI and VIII, and IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, a polypeptide encoded by a nucleic acid coding for an essential secretory gene for *Helicobacter* of Group VI can be used to make a vaccine, for example, which is a materially different method than those recited in Groups VIII and IX.

Pursuant to 35 U.S.C. 121 and 37 C.F.R. 1.141, the sequences of claims 37 and 45 are restricted to **one** sequence. The Commissioner has partially waived the requirements of 37 C.F.R. 1.141 and will permit a reasonable number of such nucleotide sequences to be claimed in a single application. Under this policy, up to 10 of independent and distinct nucleotide sequences will be examined in a single application (see MPEP 803.04 and 2434).

Claims 37 and 45 recite any one of SEQ ID NOs: 1 to 246, directed to nucleic acids and amino acid sequences. The instant sequences are considered to be unrelated, since each sequence claimed is structurally and functionally independent and distinct for the following reasons: each sequence has a unique nucleotide or amino acid sequence and each sequence is structurally distinct. Furthermore, a search of more than one (1) of the sequences claimed presents an undue burden on the Patent and Trademark Office due to the complex nature of the search and corresponding examination of more than one (1) of the claimed sequences. Further, because a separate search would be required for each one of the sequences of claims 37 and 45, restriction for examination purposes as indicated is proper. In view of the foregoing, one (1) sequence is considered to be a reasonable number of sequences for examination. Accordingly, applicants are required to elect **one** sequence from claims 37 and 45.

This is not a species requirement, but a restriction of distinct and independent inventions: unique and structurally distinct nucleotide/amino acid sequences. Applicant is required to elect one SEQ ID NO. as recited in claims 37 and 45.

Upon election of Group I, the following restriction is required to one identification method, one selection gene, one polypeptide, one development form, one category of essential genes, and one determination of potential of the polypeptide:

If Group I is elected, Applicant is required to elect one identification method. For example, either essential genes are identified by CAI or essential genes are identified by SRM, as recited in claims 2 and 3 must be elected for examination purposes. Applicant is required to elect one selection gene. For example, either the selection is carried out for specific subtracted apathogenic or pathogenic genes, or selection is carried out for specific subtracted genes of *H. phlori* or *H. heilmannii*, as recited in claims 6 and 7 must be elected for examination purposes. Applicant is required to elect one polypeptide. For example, either gene sequences coding for exported polypeptides or gene sequences coding for secreted polypeptides are selected, as recited in claims 8 and 9 must be elected for examination purposes. Applicant is required to elect one development form. For example, either the development of the vital form from the resistant form or the resistant form to the vital form, as recited in claims 10 and 11 must be elected for examination purposes. Applicant is required to elect one category of essential genes. For example, either the category of obligately essential genes or the category of facultatively essential genes, as recited in claims 13 and 14 must be elected for examination purposes. Applicant is required to elect one determination of potential of the polypeptide. For example, either a determination of the immunogenic potential of the polypeptide or the determination of the binding potential of the polypeptide, as recited in claims 17 and 18 must be elected for examination purposes.

Upon election of Group II, the following restriction is required to one method to produce gene-deficient microorganisms, one method to mutagenize the DNA section, one identifying method, and one category of essential genes:

If Group II is elected, Applicant is required to elect one method to produce gene-deficient microorganisms. For example, either the gene-deficient microorganisms are produced by mutagenizing a DNA section in a microbial genome or the gene deficient microorganisms are produced by expressing a DNA section or a part-sequence in the form of antisense RNA, as recited in claims 23 and 27 must be elected for examination purposes. Applicant is required to elect one method to mutagenize the DNA section. For example, either the DNA section is mutagenized by transposon mutagenesis or the DNA section is mutagenized by homologous recombination, as recited in claims 24 and 25 must be elected for examination purposes. Applicant is required to elect one identifying method. For example, either the SRM method is used or the CAI method is used, as recited in claims 26 and 28 must be elected for examination purposes. Applicant is required to elect one category of essential genes. For example, either the category of obligately essential genes or the category of facultativley essential genes, as recited in claims 30 and 31 must be elected for examination purposes.

Upon election of Group III, the following restriction is required to one vector comprising a nucleic acid coding for an essential secretory gene from *Helicobacter*.

If Group III is elected, Applicant is required to elect one vector comprising a nucleic acid coding for an essential secretory gene from *Helicobacter*. For example, either the vector is a CAI vector or the vector is a SRM vector, as recited in claims 40 and 41 must be elected for examination purposes.

The Examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the Examiner before the patent issues. See MPEP § 804.01.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their divergent classification and recognized divergent subject matter, and the search required for each one of Groups I-VII is not required for the other Groups, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Terra C. Gibbs whose telephone number is (571) 272-0758. The examiner can normally be reached on M-F 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader can be reached on (571) 272-0760. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

tcg
March 31, 2004

KAREN A. LACOURCIERE, PH.D
PRIMARY EXAMINER